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1. **Introduction**

1.1. Specific Directorates may wish to Trial or Evaluate Medical Devices either when reviewing options for replacing existing equipment or to take advantage of new technology.

1.2. There are a number of essential control checks in place to protect the Trust, the user and the patient when using such items.

1.3. Individuals in the Trust's Departments/Directorates might also be approached at conferences, meetings or on-site by commercial representatives endeavouring to market/sell their products. This could result in products and/or items of equipment being left for use on an on-loan/trial basis within the Trust.

1.4. Items may also be supplied directly to the point of use by the representative, or company, in good faith and with good intent. This may often be to fulfil an urgent requirement, but at the same time this, and all the other routes mentioned above avoid essential control checks.

1.5. By following the guidance contained in this Policy, unnecessary delays in obtaining equipment may be avoided and a safe system established to protect both the user and the patient. Litigation against the Trust will therefore be both managed and minimised.

2. **Purpose of this Policy**

2.1. To have a policy for The Trials and Evaluation of Medical Devices of CE marked Medical Devices, that will be used both internally by staff and shared with equipment suppliers.

2.2. To enjoy the benefits and opportunities afforded by participating in equipment trials.

2.3. To manage the use of medical equipment on trial in line with this Policy to maximise safety and minimise patient risk.

2.4. To manage the risks associated with Devices on trial and Patient involvement (ie items used on patients) through robust risk assessment by staff involved in the trial.

3. **Scope**

3.1. This policy applies to all RCHT staff that initiates or takes part in Trials and Evaluations of Medical Devices which are CE marked and currently in the market place. In addition, this policy can also be used for the trial of other items and equipment that are not classified as medical devices, as the principles of obtaining the appropriate authorization and ensuring patient and staff safety will still apply.

4. **Definitions**

4.1. **Medical Device**

“A Medical Device is defined as any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient or client for the purpose of
**Examples of Medical Devices (not exhaustive)**


**4.2. Trials**

A **Trial is to** evaluate the effectiveness and safety of medications or medical devices. A trial item will normally be left in the Trust for a certain length of time for staff to use in a clinical environment.

A **Demonstration** of a medical device involves the presentation of an item to staff to view, displayed by a representative of the company. Therefore the item is not used by staff on patients and the item is not left in the Trust.

An **Evaluation** is the assessment undertaken during a trial or demonstration to review how well an item performs. This should be against a specification.

**5. Ownership and Responsibilities**

**5.1. Role of the Trust Board and Medical Director**

The Trust Board has overall responsibility for the safe management of Medical Devices. The Medical Director has overall responsibility for the Trust's management of Medical Devices and compliance with the relevant external Assurance Standards.

**5.2. Role of the Medical Devices and Clinical Products Group**

The forum for users to discuss Trials of new devices, Maintenance, Training, and Risk & Safety issues with regards to Medical Devices:

- Provides advice to the Trust Board via the Divisional Quality Group, or equivalent, on the procurement, management and deployment of Medical Devices.
- Helps formulate common policy/procedures.
- Ratifies a Recommended List of Medical Devices.

The Trust’s Executive Director of Nursing, Midwifery and AHP and The Clinical Director of Medical Physics co chair this group and the membership consists of key individuals listed in the terms of reference document.

**5.3. Role of Staff**

It is the role of all staff who are involved with the selection, ordering, maintenance, use and delivery of Medical Devices to undertake their duties in a manner which will minimize the risk to patients and users, whilst maximizing the full potential of the equipment, both in utilisation and clinical effectiveness. Staff are reminded that they have a duty of confidentiality both to the patient and to the Trust when discussing future and ongoing trials and evaluations with commercial representatives.

- Staff must not accept samples of any products for the clinical treatment of patients within the Trust other than through the mechanisms outlined in this policy.

_A Policy for the Trial and Evaluation of Medical Devices_
Staff must treat all suppliers fairly and equitably in the operation of this policy.
All offers of hospitality or gifts made to staff must be in accordance with the
Trust Policy, Standards of Business Conduct.

5.4. Supplier/representative responsibilities
It is expected that suppliers and their representatives will comply with all currently
recognised industry codes of practice and agreed standards when visiting or dealing
with an NHS Trust and RCHT policy on Supplier Representatives visiting the Trust.

6. Standards and Practice
6.1. To avoid exposure of the Trust to significant risk posed by the Device:-

- The equipment must comply with Medical Health-care Product Regulatory
  Agency (MHRA) guidelines, which require supplier indemnity to be assured, via
  the completion of appropriate documentation.
- Staff must obtain training on the use of medical devices and be competent with
  a device before use, and have evidence of training on RCHT forms (MD04)
  Medical Device Training.
- The Lead person shall assess the risks involved with the trial.
- Staff must not infringe manufacturer's warranties and liabilities by undertaking
  inappropriate repairs to equipment, which are not in the legal ownership of the
  Trust.
- Staff must ensure that appropriate agreements are in place for the ongoing
  maintenance of equipment if on a long-term trial and inform the
  decontamination manager if relevant.
- For equipment involving ionising radiation or associated imaging equipment,
  staff must refer to the Trust’s Radiation Safety Policy.
6.2. Process for Trials/ Evaluation of Medical Devices

Trial/evaluation of medical device required

Complete the Product trial request form Appendix 1 and send to Procurement and Supplies. Ensure that the product has evidence to support its use where appropriate

Identify reasons for trial/evaluation. Identify Financial, Technical and Clinical criteria. Risk assessment

Name the product. Ensure Pre Purchase Questionnaire is completed where relevant and Master Indemnity is available.

Identify the Company contact

Establish essential & desirable criteria for the evaluation

Identify lead person for the trial and where the trial is to take place

Identify start date of the trial

Identify finish date of the trial

Trial outcomes must include, Technical, Financial and Clinical Appraisal, Training Impact

Ensure appropriate acceptance testing is carried out and relevant Departments informed

Ensure staff are trained in the use of the device before trial commences

Undertake trial/evaluation and complete Outcome Form (Appendix 2)

Send report to Medical Devices Clinical and Non-Clinical Products Group via procurement and Supplies manager

NB: The level of detail required will depend on the classification of medical device and organisational impact
6.3. Acceptance of a Medical Device on Trial

6.4. Appropriate advice must be sought in advance of any item on trial to arrange appropriate acceptance checks. Part of the acceptance process is to ensure the proper recording of the items being used. To ensure traceability in the event of any recall and any possible litigation procedures if the device is subject to any incident.

6.5. Advice can be obtained from The Clinical Equipment Management Services team, (CEMS), Radiation Physics and/ or the Sterile Supplies Service.

6.6. All Medical Devices must have appropriate safety and compliance checks carried out by suitably qualified staff before use. This may include, but not confined to, Medical Physics (Clinical Equipment and/or Radiation Protection), Control of Infection and Sterile Services.

6.7. Appropriate hospital-wide staff should be informed of the trial (eg, infection control team, patient safety team, R&D, procurement and supplies, any area who may use the item and who would be assisted by knowledge of outcome)

6.8. The RCHT requires that any equipment to be left on trial would arrive:

- Decontaminated, with appropriate certification.
- With valid Master Indemnity Insurance; this can be checked by the Trial Lead on the Department of Health website, publications section, or by contacting the Procurement and Supplies department. If the supplier is not listed on the Master Indemnity List, staff wishing to undertake the trial should contact the Procurement and Supplies team, who will provide an Indemnity Deed for completion and signature by the company and the Medical Director or Director of Nursing, Midwifery and AH Professions. The trial cannot commence until this document has been signed.
- With a loan agreement signed by company and staff member receiving item for trial noting date of trial start and end date.
- With operator’s instructions (including safety guidance & decontamination instructions) to be left with the equipment. Electronic copies made available where possible.
- With a brief competency checklist, covering important features of the product for quick referral
- With an NHS Delivery Note (which is part of the national indemnity documentation, copies of which are available from Procurement and Supplies)
- After appropriate training has been delivered by qualified personnel prior to trial commencing, with completed record of attendees for the training sessions provided to the Trust. We expect a Competency Based level of training for our Staff and end-users, to comply with the NHSLA / CNST (Clinical Negligence Scheme for Trusts) insurance requirements.

If medical related samples are not intended for patient use then they must be clearly marked as such.

6.9. Evaluation of a Medical Device on Trial

6.10. Prior to the evaluation of a Medical Device, the Product Trial Request Form (Appendix 1) must be completed and sent to the Procurement and Supplies team. This enables Procurement and Supplies to check the register to see if a trial of the same item has previously been carried out and, if not, ensures the appropriate authorization to commence the trial.
Any item on trial with a view to purchase can only be impartially evaluated against a pre-written specification. Specifications which will be used for the final assessment should be written prior to the trial commencing, based on the Essential and Desirable requirements of the item.

Essential requirements must include any National and International Standards to which the Device must conform to.

To conclude the trial, the evaluation report should cover Clinical, any Training Impact for staff using this device and Technical & Financial issues, to be undertaken by the staff group using the equipment.

A ranked score against the original specification to be completed to enable a fair assessment of the items on trial.

The Medical Device Trial Outcome form (Appendix 2) is to be completed and returned to the Procurement and Supplies department at the end of the trial period. Guidance for completion of this form can be found in Appendix 3.

At the end of the trial the device must be appropriately decontaminated and any Patient identifiable information removed before returning to the company.

6.11. Summary

6.12. A Supplier must:
- provide an NHS delivery note indicating the source of request for the item within the Trust
- be covered by indemnity form A/B, and complete a PPQ for any electrical items. A deed of Indemnity is required for any item provided by a company not on the NHS Master Indemnity Agreement. The Procurement and Supplies Department will confirm which document is required
- provide Decontamination certificate
- ensure relevant Trust acceptance tests are carried out prior to trial commencing. Advice can be obtained from The Procurement and Supplies Department.
- provide (recorded) competency based training on item prior to trial commencing
- provide up to date instruction manuals, user guides and technical information.
- ensure arrangements are in place for item to be returned to them at the end of the trial (date, method of return) where relevant.

6.13. Lead person must:
- set a list of specification for the trial assessment, prior to commencement (see evaluation form)
- inform The Procurement and Supplies Department of any item due on trial prior to commencement via the completion of the Product Trial Request Form (Appendix 1)
- Carry out risk assessment.
- ensure all relevant staff in RCHT are aware of trial
- ensure any items have been Acceptance checked
- ensure staff are trained prior to trial
complete a Medical Device Trial Evaluation form at the end of the trial (see Appx 2)
ensure that all patient identifiable information is removed from the equipment before release back to the supplier.
decontaminate item and ensure arrangements are made for removal from Trust by company at end of trial (where relevant)
not commit to purchase of any trial item without referral to the Procurement and Supplies department, in order to ensure that the Trust is not already committed to a contractual arrangement or may need to undertake a tendering exercise

6.14. **All staff must:**
- be aware of the trial
- not use the item on trial unless appropriately trained

7. **Dissemination and Implementation**

7.1. This policy will be published on the Trust Document Library following authorisation by the Executive Director. Immediately following publication the Medical Physics Department will ensure that its publication is highlighted across the Trust using various media including the Daily Bulletin. Implementation of this policy will be supported through a series of briefings, departmental visits and training as required.

7.2. The training aspects relating to the implementation of this policy are contained within the main body of this document.

8. **Monitoring compliance and effectiveness**

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Monitoring of policy documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>‘Medical Device Trial Outcomes’</td>
</tr>
<tr>
<td></td>
<td>Appendix1</td>
</tr>
<tr>
<td>Lead</td>
<td>Assurance of compliance will be subject to audit by the Medical Devices Co-Ordinator.</td>
</tr>
<tr>
<td>Tool</td>
<td>Information to be obtained from ‘Medical Device Trial Outcomes’ Document to ensure compliance with policy documentation.</td>
</tr>
<tr>
<td>Frequency</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Biannual reports on the Management of Medical Devices are presented to the Divisional Quality Group and the Trust Board. A report will be produced for the Divisional Quality Group. The information will be summarized on the annual IPR report to the executive board. Reports will be reviewed by the Medical Devices and Procurement Committee.</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Lead for actions will be held by Medical Devices Co-Ordinator. Any identified actions will be completed within 6 months.</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Medical Devices and Procurement Committee. Medical Devices Links. Medical Devices News Letter</td>
</tr>
</tbody>
</table>
9. **Updating and Review**

9.1. This policy will normally be reviewed no less than every three years unless an earlier review is required.

10. **Equality and Diversity**

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

**10.2. Equality Impact Assessment**

The Initial Equality Impact Assessment Screening Form is at Appendix 5.
Appendix 1. Product Trial Request Form

<table>
<thead>
<tr>
<th>Product Description:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code:</td>
<td></td>
</tr>
<tr>
<td>Supplier:</td>
<td></td>
</tr>
<tr>
<td>Purpose of Trial: (provide details)</td>
<td></td>
</tr>
</tbody>
</table>

- Like for like replacement: Y N
- Updated version of same product: Y N
- New product to the Trust: Y N

### Product Specifications

<table>
<thead>
<tr>
<th>Essential</th>
<th>Desirable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cost per unit of this item:</strong></td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Is the product free of charge for the trial?</strong></td>
<td>Y</td>
</tr>
<tr>
<td><strong>Number of units required for trial:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Detail any additional equipment/accessories/consumables necessary for trial to proceed:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Trial date:</strong></td>
<td>From</td>
</tr>
<tr>
<td><strong>Department(s) and division(s) involved:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lead person name and contact details:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Risk assessment of trial</strong></td>
<td>Y</td>
</tr>
<tr>
<td><strong>Manufacturer’s Decontamination instructions available? (for re-usable devices)</strong></td>
<td>Y</td>
</tr>
<tr>
<td><strong>Location of trial:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Provider and method of Training for this Device/Product</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Supplier &amp; Rep contact details:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Signature</strong></td>
<td>Date</td>
</tr>
<tr>
<td><strong>DGM Approval</strong></td>
<td>Date</td>
</tr>
</tbody>
</table>

**To be completed by Procurement/Supplies**

<table>
<thead>
<tr>
<th><strong>On going cost impact:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>On going cost of additional equipment/ accessories/ consumables:</strong></td>
</tr>
<tr>
<td><strong>Is the supplier established within the NHS?</strong></td>
</tr>
<tr>
<td><strong>Is the product on National Contract?</strong></td>
</tr>
<tr>
<td><strong>Indemnity cover confirmed?</strong></td>
</tr>
<tr>
<td><strong>Approval from Procurement Group?</strong></td>
</tr>
<tr>
<td><strong>Allocated Trial Reference Number:</strong></td>
</tr>
</tbody>
</table>
Appendix 2. Medical Device Trial Outcomes

*Once completed please send this form to the Supplies & Procurement Department
Please use extra sheets if required*

| Reason(s) for undertaking evaluation: note names of other items on trial for same evaluation |
| Make, Model, Product Code, |
| Company Contact |
| Original specification of trial evaluation |
| Essential: | Desirable: |
| Start date of Trial | Finish date of Trial |
| Name(s) of Lead Person for trial: | Area(s) in which the trial takes place: |
| Comments on equipment performance: Specifications met? |

Clinical evaluation specification and ranked score (see Appendix 3) for this piece of equipment:
*(to cover Clinical Technical overview & Financial life-costs)*

These sections may be completed by other relevant departments/senior staff

1 Financial

2 Technical

3 Clinical To Include Impact on Training needs

| Signed | Designation/Grade | Date |
| Name | Location Hosp/ward | Ext No |
Appendix 3. Guidance Notes for Completion of the Medical Device Trial Outcome Form

(For form, see Appendix 2)

The evaluation specification should be specific to the type of equipment being evaluated.

The evaluation specification should be divided into two categories – ESSENTIAL and DESIRABLE, and be of a generic nature, i.e. the specification should not be written around the specification of a particular (favoured) piece of equipment, since the specification should be able to stand scrutiny by independent sources.

The scoring table at the end of these guidance notes can be used to score the following specification.

When evaluating equipment there are three main components to take into consideration:–
- Clinical
- Technical
- Financial

The Clinical component should be undertaken by the staff group who would use the equipment, should acquisition take place. Prior to the evaluation, a specification and ranking should be agreed against which the equipment will be ‘scored’.

The Technical component will relate to the maintenance, performance and compliance to relevant standards.

For the Financial component assistance may be required from the Financial Department, the Supplies and Procurement Department, the Medical Physics Department and the staff group requiring the equipment.

The aim is that the WHOLE LIFE COST of the equipment is established.

Whole Life Costs include –
- Purchase price of equipment
- Depreciation costs over the life of the equipment
- Approx. cost of consumables over the expected life of the equipment
- Warranty period of equipment
- Cost of maintenance
- Cost of staff time, e.g. training, additional work
- Standardisation to existing equipment

Note:
The lowest purchase price of the product does not necessarily mean the lowest whole life cost.
## Ranked Scoring Table

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
<th>Full Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Exceptional</td>
<td>Full achievement of the requirements specified. Demonstrated strengths, no errors, weaknesses or omissions.</td>
</tr>
<tr>
<td>4</td>
<td>Superior</td>
<td>Sound achievement of the requirements specified. Some minor errors, risks, weaknesses or omissions, which may be acceptable as offered.</td>
</tr>
<tr>
<td>3</td>
<td>Good</td>
<td>Reasonable achievement of the requirements specified. Some errors, risks, weaknesses or omissions, which can be corrected/overcome with minimum effort.</td>
</tr>
<tr>
<td>2</td>
<td>Adequate</td>
<td>Satisfactory achievement of the requirements specified. Some errors, risks, weaknesses or omissions, which are possible to correct/overcome and make acceptable.</td>
</tr>
<tr>
<td>1</td>
<td>Inadequate</td>
<td>Minimal achievement of the requirements specified. Several errors, risks, weaknesses or omissions, which are possible, but difficult to correct/overcome and make acceptable.</td>
</tr>
<tr>
<td>0</td>
<td>Poor to Unacceptable</td>
<td>No achievement of the requirements specified. Existence of numerous errors, risks, weaknesses or omissions, and non-compliance of recognised standards</td>
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</table>
### Appendix 4. Governance Information

<table>
<thead>
<tr>
<th><strong>Document Title</strong></th>
<th>A Policy for The Trial and Evaluation of Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date Issued/Approved:</strong></td>
<td>22 July 2014</td>
</tr>
<tr>
<td><strong>Date Valid From:</strong></td>
<td>26 August 2014</td>
</tr>
<tr>
<td><strong>Date Valid To:</strong></td>
<td>31 August 2014</td>
</tr>
<tr>
<td><strong>Directorate / Department responsible (author/owner):</strong></td>
<td>Philip Conroy, Head of Clinical Technology, Medical Physics</td>
</tr>
<tr>
<td><strong>Contact details:</strong></td>
<td>01872 252496</td>
</tr>
<tr>
<td><strong>Brief summary of contents</strong></td>
<td>This policy is intended for use by those involved in any trial of a Medical Device on behalf of RCHT</td>
</tr>
<tr>
<td><strong>Suggested Keywords:</strong></td>
<td>Trials, Evaluations</td>
</tr>
<tr>
<td><strong>Target Audience</strong></td>
<td>RCHT, PCH, CFT, KCCG</td>
</tr>
<tr>
<td><strong>Executive Director responsible for Policy:</strong></td>
<td>Executive Director of Nursing, Midwifery and AHP</td>
</tr>
<tr>
<td><strong>Date revised:</strong></td>
<td>20 May 2014</td>
</tr>
<tr>
<td><strong>This document replaces (exact title of previous version):</strong></td>
<td>A Policy for The Trial and Evaluation of Medical Devices v2.0</td>
</tr>
<tr>
<td><strong>Approval route (names of committees)/consultation:</strong></td>
<td>Medical Devices and Procurement Committee, CSSC Governance DMB</td>
</tr>
<tr>
<td><strong>Divisional Manager confirming approval processes</strong></td>
<td>Bruce Daniel, Divisional General Manager, Clinical Support Services &amp; Cancer Division</td>
</tr>
<tr>
<td><strong>Name and Post Title of additional signatories</strong></td>
<td>Janet Gardner, Governance Lead CSSC</td>
</tr>
<tr>
<td><strong>Signature of Executive Director giving approval</strong></td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td><strong>Publication Location (refer to Policy on Policies – Approvals and Ratification):</strong></td>
<td>Internet &amp; Intranet ✓ Intranet Only</td>
</tr>
<tr>
<td><strong>Document Library Folder/Sub Folder</strong></td>
<td>Clinical / Medical Physics</td>
</tr>
<tr>
<td><strong>Links to key external standards</strong></td>
<td>N/A</td>
</tr>
</tbody>
</table>
| **Related Documents:** | • Medical Devices Management Policy  
• RCHT Procurement Policy  
• Standing Financial Instructions,  
• Scheme of Delegation,  
• Standards of Business Conduct,  
• Staff Guide to Standing Financial... |
Instructions
- Managing Medical Devices DB2006(05).
- Decontamination Policy

Training Need Identified? No

**Version Control Table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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</thead>
<tbody>
<tr>
<td>31/05/2011</td>
<td>1.0</td>
<td>New Policy</td>
<td>P Conroy / Sally-Anne Basey</td>
</tr>
<tr>
<td>10/04/2013</td>
<td>2.0</td>
<td>Updated Forms and wording</td>
<td>P Conroy/ H Newton/ M Lavery</td>
</tr>
<tr>
<td>29/05/14</td>
<td>2.1</td>
<td>Updated forms and wording</td>
<td>P Conroy/H Newton</td>
</tr>
</tbody>
</table>

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

**Controlled Document**
This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.
### Appendix 5. Initial Equality Impact Assessment Screening Form

<table>
<thead>
<tr>
<th>Name of service, strategy, policy or project (hereafter referred to as policy) to be assessed:</th>
<th>A Policy for the Trial and Evaluation of Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate and service area:</td>
<td>Medical Physics, CSSC Division</td>
</tr>
<tr>
<td>Is this a new or existing Policy?</td>
<td>Existing</td>
</tr>
<tr>
<td>Name of individual completing assessment:</td>
<td>P Conroy</td>
</tr>
<tr>
<td>Telephone:</td>
<td>01872 252497</td>
</tr>
</tbody>
</table>

#### 1. Procedure Aim*
Outlines and guidance for Medical Devices on Trial or for Evaluation

#### 2. Procedure Objectives*
To ensure Medical Devices entering the Trust are used safely and effectively during evaluation and trials. To advise those leading the trial on their roles and responsibilities.

#### 3. Procedure – intended Outcomes*
To enjoy the benefits and opportunities afforded by participating in equipment trials.

#### 4. How will you measure the outcome?
Incident numbers and CQC inspection

#### 5. Who is intended to benefit from the Procedure?
All staff and patients.

#### 6. Is consultation required with the workforce, equality groups etc. around this procedure?
Yes

b. If yes, have these groups been consulted?
Yes

c. Please list any groups who have been consulted about this procedure.
Medical Devices and Clinical Products Group

#### 7. The Impact
Please complete the following table.

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race / Ethnic communities /groups</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Disability - Learning disability, physical disability, sensory impairment and mental health problems
Religion / other beliefs
Marriage and civil partnership
Pregnancy and maternity
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
• You have ticked “Yes” in any column above and
• No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
• Major service redesign or development

8. Please indicate if a full equality analysis is recommended.
   Yes  No ✓

9. If you are not recommending a Full Impact assessment please explain why.
   No concerns identified regarding differential impact

Signature of policy developer / lead manager / director  Date of completion and submission

Names and signatures of members carrying out the Screening Assessment
1. P Conroy
2.

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed ____________________

Date ____________________